



29 April 2021

(21-3664)

Page: 1/3

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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| 1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved: |
| 2. Agency responsible: European Commission, Health and Food Safety Directorate-General |
| 3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Preparation of a kind used in animal nutrition (HS Code: 2309) |
| 4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries: |
| 5. Title of the notified document: Commission Implementing Regulation (EU) 2021/669 concerning the authorisation of technically pure L-lysine monohydrochloride and liquid L-lysine base produced by <i>Corynebacterium casei</i> KCCM 80190 or <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP as feed additives for all animal species (Text with EEA relevance). Language(s): English, French and Spanish. Number of pages: 7 https://members.wto.org/crnattachments/2021/SPS/EEC/21_3138_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_3138_00_f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_3138_00_s.pdf |
| 6. Description of content: Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. In accordance with Article 7(1) of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of liquid L-lysine base and technically pure L-lysine monohydrochloride as nutritional feed additives for use in feed and in water for drinking for all animal species. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. The applications concern the authorisation of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by <i>Corynebacterium casei</i> KCCM 80190 or <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP as feed additives for all animal species to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'. The European Food Safety Authority ('the Authority') concluded in its opinions of 30 September 2020 and 18 November 2020 that, under the proposed conditions of use, L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by <i>Corynebacterium casei</i> KCCM 80190 or <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP do not have an adverse effect on animal health, consumer health or the environment. The Authority could conclude on the safety for the user of the L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by <i>Corynebacterium glutamicum</i> KCCM 80216 and <i>Corynebacterium</i> |

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| <p><i>glutamicum</i> KCTC 12307BP. It stated that of L-lysine monohydrochloride, technically pure, and L-lysine base, liquid, produced by <i>Corynebacterium casei</i> KCCM 80190 are considered hazardous by inhalation and that L-lysine monohydrochloride, technically pure, produced by <i>Corynebacterium casei</i> KCCM 80190 is a mild eye irritant. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by <i>Corynebacterium casei</i> KCCM 80190 or <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP, are effective sources of the essential amino acid L-lysine for all animal species. For the supplemental L-lysine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. In its opinions, the Authority referred to a previous statement concerning potential nutritional imbalances for amino acids and hygienic concerns, when they are administered via water for drinking. However, the Authority did not propose a maximum content for the supplementation with L-lysine. Thus, it is appropriate to indicate on the label of the additive, and premixtures containing it, an alert to take into account the dietary supply with all the essential and conditionally essential amino acids, particularly in the case of supplementation with L-lysine as amino acid via water for drinking.</p> |
| <p>7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.</p> |
| <p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input checked="" type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): Code of practice on Good Animal Feeding CAC/RCP 54-2004</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p> |
| <p>9. Other relevant documents and language(s) in which these are available:</p> |
| <p>10. Proposed date of adoption (dd/mm/yy): 23 April 2021</p> <p>Proposed date of publication (dd/mm/yy): 26 April 2021</p> |
| <p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.</p> <p><input checked="" type="checkbox"/> Trade facilitating measure</p> |
| <p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels</p> |

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13. Text(s) available from: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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